

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and )  
EDWARDS LIFESCIENCES LLC, )  
Plaintiffs, )  
v. ) C.A. No. \_\_\_\_\_  
COREVALVE, INC., ) DEMAND FOR JURY TRIAL  
Defendant. )

**COMPLAINT**

Plaintiffs Edwards Lifesciences AG (“Edwards AG”) and Edwards Lifesciences LLC (“Edwards LLC”) (collectively, “Plaintiffs”), for their Complaint against Defendant CoreValve, Inc. (“CoreValve”), allege as follows:

**JURISDICTION AND VENUE**

1. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. This Court has jurisdiction over the subject matter of this action based on 28 U.S.C. §§ 1338(a) and 1331. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because CoreValve resides in this Judicial District.

**THE PARTIES**

2. Plaintiff Edwards AG is a corporation organized and existing under the laws of Switzerland and having its principal executive offices in St.-Prex, Switzerland.

3. Plaintiff Edwards LLC is a limited liability company organized and existing under the laws of the State of Delaware and having its principal executive offices in Irvine, California.

4. Edwards AG is the assignee of the following United States Patents covering pioneering percutaneous heart valve products and methods of their use: U.S. Patent

No. 5,411,552, U.S. Patent No. 6,168,614, and U.S. Patent No. 6,582,462 (collectively, "Patents"). The Patents disclose and claim, *inter alia*, collapsible and expandable tissue valve prostheses and methods for replacing human heart valves using minimally invasive catheterization procedures.

5. Edwards LLC is the exclusive licensee of the Patents for the field of all cardiovascular applications.

6. Upon information and belief, Defendant CoreValve is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Irvine, California.

7. Upon information and belief, CoreValve manufactures in the United States heart valve prostheses known as the "ReValving" system that infringe the Patents.

8. Upon information and belief, CoreValve has obtained European CE mark approval for its ReValving heart valve prostheses, and is currently offering its ReValving system for commercial sale in Europe.

**FIRST CAUSE OF ACTION**  
**(For Infringement of the '552 Patent)**

9. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 8 above.

10. On May 2, 1995, U.S. Patent No. 5,411,552 ("552 Patent") (Exh. 1 hereto), entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '552 Patent for the field of all cardiovascular applications. Plaintiffs are

the owners of all rights, title and interest in and to the '552 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

11. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '552 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '552 Patent, including without limitation products designated as the ReValving system.

12. CoreValve's foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

13. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

**SECOND CAUSE OF ACTION**  
**(For Infringement of the '614 Patent)**

14. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 13 above.

15. On January 2, 2001, U.S. Patent No. 6,168,614 ("'614 Patent") (Exh. 2 hereto), entitled "Valve Prosthesis for Implantation in the Body," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '614 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '614 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

16. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '614 Patent by supplying or causing to be supplied

in or from the United States a component of the invention claimed in the '614 Patent, including without limitation supplying the ReValving system, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the '614 Patent if such combination occurred in the United States.

17. CoreValve's foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

18. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

**THIRD CAUSE OF ACTION**  
**(For Infringement of the '462 Patent)**

19. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 18 above.

20. On June 24, 2003, U.S. Patent No. 6,582,462 ("'462 Patent") (Exh. 3 hereto), entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive sublicensee of the '462 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '462 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

21. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '462 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '462 Patent, including without limitation products designated as the ReValving system.

22. CoreValve's foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

23. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

#### **PRAYER FOR RELIEF**

WHEREFORE Plaintiffs demand judgment as follows:

(a) Finding that CoreValve has infringed the '552 Patent, the '614 Patent and the '462 Patent;

(b) Finding that CoreValve's infringement has been willful and deliberate;

(c) Preliminarily and permanently enjoining and restraining CoreValve, its officers, agents, servants, employees and attorneys, all parent, subsidiary and affiliate corporations and other related business entities, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '552 Patent, the '614 Patent and the '462 Patent;

(d) Awarding Plaintiffs damages, in an amount to be determined at trial, together with interest and costs as fixed by the Court;

(e) Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284;

(f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285; and

(g) Granting Plaintiffs such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiffs demand a trial by jury on all issues so triable in this Complaint.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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